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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,747	12/07/2001	Lorrie P. Daggett	SD9383CDB	3880

7590 11/17/2003

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,747	DAGGETT ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-45* is/are pending in the application.

4a) Of the above claim(s) *41-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) Claims 37 to 45 are pending in the instant application.

2) Claims 41 to 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the correspondence filed 28 August of 2003. The traversal is on the ground(s) that a search for the claimed polypeptide would "of necessity," include a search for the claimed antibodies. This is not found persuasive because antibodies are routinely produced against proteins that have never been purified. Further, proteins have been purified and used without antibodies having ever made thereto. The traversal is essentially on the ground(s) that a search of the different inventions in a single application would pose no undue burden. This is not found persuasive because M.P.E.P. 803 states that:

> " For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant."

Serious burden was shown in the original requirement by the separate classification and separate status in the art of the different inventions. Applicant has provided neither a showing or evidence to the contrary.

The requirement is still deemed proper and is therefore made FINAL.

3) The amendment that was filed on 07 December of 2001 was not entered because it did not comply with 37 C.F.R. § 1.121.

4) The instant specification is objected to because it does not contain a description of Figures 2A and 2B. Any reference contained therein to a "Figure 2" should be changed to "Figure 2A" and/or "Figure 2B".

5) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. The text on page 9 of the instant specification, for example, is employing both sequence identifiers and sequence numbers in an incorrect format such as "Sequence ID No:" and "2E". Correction is required. See M.P.E.P. 2422.03.

6) Applicant is advised that should claim 37 be found allowable, claim 39 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. Claim 39 does not further limit claim 37 because the only receptor subtype identified as being encoded by SEQ ID NO:57 is an NMDAR2D subunit. See MPEP § 706.03(k).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7) Claims 37 to 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims require the production of an NMDA **receptor** subtype encoded by SEQ ID NO:57 or comprising the amino acid sequence of SEQ ID NO:58. The art of molecular biology defines a "receptor" as a protein or protein complex that binds a ligand molecule and induces a physiological change in the cell expressing it, without altering the structure of the ligand. As explained in the abstract of the instant specification, the proteins described therein are NMDA receptor **subunits**. An NMDA **receptor** of the instant invention is a protein complex composed of five subunits in a heteropentameric structure that functions as a glutamate-gated ion channel. SEQ ID NO:58 of the instant application does not correspond to an NMDA receptor, it is the amino acid sequence of a specific NMDA receptor subunit. Claim 39 requires the claimed receptor to be a receptor subunit. The instant specification does not provide the guidance needed to produce a receptor that is composed only of a protein comprising the amino acid sequence presented in SEQ ID NO:58 of the instant application because there is no evidence or sound scientific reasoning of record that supports a conclusion that such a protein is capable of functioning as a receptor in the absence of other, specific, NMDA receptor subunits. In fact, the text at the top of page 29 of the instant specification and the data presented in table 1 beginning on page 66 therein appear to indicate that an NMDAR1 receptor subunit must be present an NMDA receptor complex of the instant invention before it will function. Therefore, one can not

produce a receptor encoded by SEQ ID NO:57, as required by the claims. These claims should be directed, for example, to "an isolated and substantially pure N-methyl-D-aspartate receptor subunit comprising the amino acid sequence set fourth in SEQ ID NO:58".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8) Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Because the instant specification does not identify that material element or combination of elements which is unique to and, therefore, definitive of an " N-methyl-D-aspartate receptor type 2D subunit" it is not possible to determine what is excluded or encompassed by this term. The text on pages 9 to 11 of the instant specification only identifies some properties which are "generally present" or "generally absent" from an "NMDAR2D receptor subunit".

9) Applicant is advised that a claim to "a substantially pure protein comprising the amino acid sequence set fourth in SEQ ID NO:58" would be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.